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|--|-------------|-----------------------------|---------------------|------------------|
| 10/715,826   | 11/19/2003  | J. Donald Hill              | 018880.0149         | 3645             |
| 24735 7590 08/25/2009<br>BAKER BOTTS LLP<br>C/O INTELLECTUAL PROPERTY DEPARTMENT<br>THE WARNER, SUITE 1300<br>1299 PENNSYLVANIA AVE, NW<br>WASHINGTON, DC 20004-2400 |             |                             |                     |                  |
| EXAMINER<br>ERIZO, DARWIN P  |             |                             |                     |                  |
| ART UNIT<br>3773   |             | PAPER NUMBER                |                     |                  |
| NOTIFICATION DATE<br>08/25/2009  |             | DELIVERY MODE<br>ELECTRONIC |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/715,826

**Applicant(s)**

HILL ET AL.

**Examiner**

Darwin P. Erez

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12, 23-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 27-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)  
Paper No(s)/Mail Date 12/23/08.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group I in the reply filed on 6/15/09 is acknowledged.
2. Claims 23-25, 27-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected embodiment, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/15/09.

***Information Disclosure Statement***

3. The information disclosure statement(s) (IDS) submitted on 12/23/08 has been received and made of record. Note the acknowledged form PTO-1449 enclosed herewith.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
7. Claims 1-3, 5-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0192604 to Carson et al. and in view of US 2002/0161383 to Akin et al., and in further view of US 5,456,714 to Owen.

Regarding claim 1, Carson discloses a coupler comprising: a saddle (14, fig.1A); a channel (thickened, widened portion of conduit 18, fig. 3C), wherein said channel comprises a first end having a substantially elliptical cross-section connected to said saddle (at connection of channel to Vessel wall W, fig. 3D; I, fig 5A) and a second end having a substantially circular cross-section (at distal end of the thickened, widened channel portion of conduit 18, fig. 3C). A tube or conduit with a round cross-section will attain an oval or elliptical cross section when it is cut at an angle. Therefore, the tube is round at one end, and has an elliptical shaped opening where it attaches to the saddle. Additionally, due to the curvature of the saddle where the tube attaches to it, the aperture in that end of the tube would never be "circular"; a tissue clamp positioned

around said channel (16, fig. 1A); and a flange formed adjacent to said second end of said channel (34, fig. 1A, 3C).

Carson is silent with regards to the saddle having a longitudinal axis and the channel extending along a second direction substantially perpendicular to the longitudinal axis. Instead, Carson discloses the channel to be in an angle (obtuse or acute, depending on point of view) that is not 90 degrees.

However, the use of connectors in end-to-side anastomosis having a substantially 90 degree configuration between the saddle portion and the channel is well known in the art. For example, Akin discloses such arrangement in Fig. 13. Therefore, since such arrangement was previously disclosed in the art, one of ordinary skill in the art would have found it obvious to modify the device of Carson to have the configuration of Akin. The modified device of Carson would work similar to the device of Akin, thus providing predictable results to the skilled artisan.

Carson also fails to teach that the tissue clamp is configured to elastically move from a clamped position substantially corresponding to a shape of said saddle to an unclamped position not corresponding to the shape of the saddle. Instead, the tissue clamp of Carson is always configured to the shape of the saddle in both deployed and undeployed state.

However, using a tissue clamp that is elastically deformable is well known in the art. Owen discloses a tissue coupler also comprising a tissue clamp 4, wherein the tissue clamp has an unclamped position not corresponding to the shape of flange element 2, and a clamped position that is deformed to correspond to the shape of the

flange element 2 within the blood vessel (see Figs. 5 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at time the invention was made to make the tissue clamp of Carson to be elastically deformable, as taught by Owen, because it would allow the tissue clamp to conform to the shape of the saddle and any tissue that is clamped between the saddle and the tissue clamp.

Regarding claims 2, 3, & 12, Carson discloses tissue clamp comprises a shape-memory alloy, and that shape memory alloy comprises a nickel titanium, also known as nitinol (para.0079).

Regarding claim 5, Carson discloses the tissue clamp comprising a plurality of dimpled holes formed there through (fig. 9A, 9B).

Regarding claim 6, Carson discloses the cross-sectional area of said channel's inner surface to be substantially constant as said channel transitions from said first end to said second end (lumen of channel 18, fig. 3C).

Regarding claim 7, Carson discloses the cross-sectional area of said channel increases or decreases as said channel transitions from said first end to said second end (exterior of channel 18, fig. 3C).

Regarding claim 8, Carson discloses a mating surface formed adjacent to said flange (in between flanges 34, fig. 3D).

8. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0192604 to Carson et al. and in view of US 2002/0161383 to Akin et al. and US 5,456,714 to Owen, as applied to the rejections to claim 1 above, and in further view of WO 00/24339 to Berreklouw.

Regarding claim 4, the modified device of Carson discloses a tissue clamp, but does not expressly disclose teeth along the periphery of the clamp. Berreklouw teaches a tissue clamp (45, fig. 8) with teeth (26, fig. 8) along the perimeter of the tissue clamp. This arrangement has the apparent advantage of ensuring better connection between the tissue clamp and the vessel. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the tissue clamp of Carson to include teeth, as taught by Berreklouw to obtain the same advantage.

Regarding claim 9, the modified device of Carson discloses a tissue clamp, but fails to expressly teach a pair of legs on the tissue clamp. However, Berreklouw teaches another embodiment of a tissue clamp (115, fig. 5) with a pair of legs (114, fig. 5) which can be extended and positioned accordingly to another part of the anastomosis device (K, fig. 4) to create adequate clamping force. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the tissue clamp of Carson to include legs as taught by Berreklouw in order to have the tissue clamped adequately to the saddle.

9. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0192604 to Carson et al. and in view of US 2002/0161383 to Akin et al. and US 5,456,714 to Owen, as applied to the rejections to claim 1 above, and in further view of US 6,814,750 to Kavteladze et al.

The modified device of Carson discloses the claimed invention except that the material is made from a material having an austenitic temperature below 10 degrees Celsius. However, Kavteladze discloses that the transformation temperature of austenitic state nickel titanium alloy is below the normal temperature of a human body

(co1.10, lines 43-48), which would allow the material to exhibit relatively high tensile strength and be stable. Below ten degrees includes the range below body temperature, hence, since the tissue clamp disclosed by Carson is made from nickel titanium, the tissue clamp would also exhibit the property of having an austenitic transition temperature below 10 degrees Celsius. Therefore, it would be obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson can be modified as taught by Kavteladze to exhibit the same advantage stated above.

10. Claims 4 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0192604 to Carson et al. and in view of US 2002/0161383 to Akin et al. and US 5,456,714 to Owen, as applied to the rejections to claim 1 above, and in further view of US 6,554,848 to Boylan et al.



The modified device of Carson discloses the invention substantially as claimed above. Carson does not disclose that the material has an austenitic temperature equal to or greater than body temperature. Boylan, however, discloses making a device implantable within the body with a nickel titanium alloy having an austenitic phase above body temperature, or 37 degrees Celsius (claim 14), which would allow the material to exhibit relatively high tensile strength and be stable. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson is modified as taught by Boylan to obtain the same advantage.

#### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezó whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezó/  
Primary Examiner, Art Unit 3773